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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/116,873	09/03/1993	GREGOR J. SUTCLIFFE	SCRF32.0DIVI	6883

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EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/116,873	SUTCLIFFE, GREGOR J.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication mailed August 6, 2004. Applicant notes that claim 31 was indicated as allowable before the appeal was taken. In accordance with Applicant's suggestion, claim 31 has been rejoined. Therefore, claims 26-33 are under examination.

The rejection of the claims under the first and second paragraphs of 35 U.S.C. 112 is maintained. Claims 26-33 are further rejected for failing to satisfy the utility and written description requirements of 35 U.S.C. sections 101 and 112 respectively. The claim rejections are as follows.

35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26, 29 and 32 are indefinite for reciting "neuroactive." As set forth in the previous Office Action, the Remand from the Board, and the Response to Arguments below, the term "neuroactive" fails to claim the inventive polynucleotide with sufficient clarity.

Dependent claims 27, 29, 30 and 33 lack antecedent basis for each limitation that is preceded by "the." For example, claim 27 begins "[t]he DNA of claim 26 that is double

stranded." A double-stranded DNA does not however appear in claim 26. Thus, the dependent limitations presented in this manner lack antecedent basis.

Claims 26, 28 and 29 are indefinite in the recitation of "complimentary." This term is indefinite because it does not make it clear whether "complimentary" means (1) that the claimed DNA completely compliments (i.e. hybridizes with) a cytoplasmic messenger RNA (mRNA) that is the same size, or (2) that the claimed DNA is partially complimentary to a mRNA that is larger than 1,800 bases provided in the claims. Note that if Applicant amends the claims to provide that the inventive DNA that is completely complimentary, claim 28 would be rendered indefinite. This is because a DNA of 500 to about 1,800 nucleotides (i.e. the DNA of claim 26) cannot completely compliment the larger mRNA of claim 28 which may be up to 10,000 bases.

Claims 26 is indefinite in the recitation of "DNA." This language is indefinite because it is unclear whether Applicant's use of "DNA" refers to a double-stranded or single-stranded polynucleotide. Note that if claim 26 is amended to clarify that it is drawn to a double-stranded polynucleotide, claim 27 would be objectionable for failing to further limit a preceding claim.

35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicant claims the cDNA of every neuroactive mammalian proteinoid that is expressed in the mammalian brain, but not in the cells of the mammal's liver, kidney, gut, lung, heart or skeletal muscles. Because the claims do not require the protein to possess any particular distinguishing feature, specific biologic activity, or conserved structure, the claims are drawn to a genus of polypeptides that are only vaguely defined by an activity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. Here, the claimed genus is mammalian cDNAs that encode "neuroactive" proteinoids. However, none of the factors listed above support a finding that Applicant were in possession of this genus. There is no disclosure of a set of specific or physical or chemical properties that defines the Applicant's neuroactive proteinoids. Rather, Applicant's genus of proteinoids is defined as those that impart increased nerve activity when applied to rat brain *in vivo*. The specification also fails to provide any functional characteristics or structre/function correlation. This is because there is no disclosure of how the claimed genus of neuroactive proteinoids achieves increased neural activity. Similarly, there is no discussion of a mechanism of action for Applicant's proteinoids and an indication of the pathways that are modulated is completely lacking. Accordingly, in the absence of sufficient

recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claims 26-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

Undue experimentation is defined by a number of factors, including: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Here, Applicant claims a mammalian cDNA that encodes a neuroactive proteinoid that is present in the brain, but not the liver, kidney, gut, lung, heart or skeletal muscle. Although the sequences of some neuroactive proteins were known at the time the parent application was filed, Applicant's specification fails to disclose a single neuroactive proteinoid sequence – the P1, P2 and P3 sequences disclosed throughout the figures have not been shown to be neuroactive. Moreover, modern proteomics reveals that a great number of proteins are expressed in the brain, yet the function of most of them is unknown. Thus, there is a great deal of unpredictability in determining those brain proteins that are neuroactive, let alone their cDNA sequences. Applicant's specification provides little guidance in overcoming this obstacle. Rather than

disclosing neuroactive gene sequences, the content of the disclosure relates to the relative distribution of a variety of proteins. These proteins are not shown to be neuroactive and Applicant extrapolates their neuroactivity based on their abundance in the brain. Based on this scant disclosure, and the lack of predictability in determining the sequences that encode neuroactive proteinoids, one of ordinary skill in the art would have to perform undue experimentation in order to practice the claimed invention.

Note that the specification also fails to enable the invention because it fails to disclose a specific and substantial utility. As noted under the utility rejection below, the specification does not describe any manner in which the claimed neuroactive cDNA could be applied in a specific, useful way. Thus, the specification fails to teach one skilled in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 26-33 are rejected under 35 U.S.C. 101 because the claimed invention lacks a specific and substantial utility. Applicant's invention is drawn to a cDNA for a neuroactive proteinoid. However, the specification fails to disclose any examples of how such cDNA, or its encoded protein, can be applied in a specific, useful way. The specification details the distribution of a variety of mRNAs, but it does not indicate how they may be used. In short, the specification lacks any disclosure of a therapeutic or diagnostic use for the claimed genus of polynucleotides. Moreover, the state of the art has not recognized a use for a cDNA that encodes

a neuroactive proteinoid. Accordingly, the claimed invention lacks a specific and substantial utility.

Response to Arguments

Applicant correctly notes that contrary to the Examiner's interpretation, the claims do not require every mRNA that is exclusive to the brain to possess a neuroactive function. Thus, the remarks regarding this construction of the claims are moot.

35 U.S.C. 112, Second Paragraph

Applicant argues the term "neuroactive" is not indefinite and that the rejection of the claims on this basis should be withdrawn. Applicant supports this suggestion with an exhibit that shows that the term "neuroactive" appeared in approximately 150 publications. The Examiner respectfully submits that this is not evidence that the term describes the invention with particularlity. Taking the mere number of occurrences of "neuroactive" out of its context does not prove that the term has a certain and definite meaning. In fact, the publications cited by Applicant relate to the neuroactive function of such diverse products as amino acids, peptides, and small molecules. Given the profound differences in the structure and activities of these products, providing that they are all "neuroactive" does not provide any clarity as to how they work. Furthermore, the term "neuroactive" could refer to very different neuron activities and functions. Does the providing that the claimed proteinoid is neuroactive imply that it behaves as an agonist that activates a specific receptor? Or, does "neuroactive" mean that the proteinoid functions intracellularly by phosphorylating an intermediate in a G-protein coupled receptor

pathway. Given the broad range of possible functions and activities described by "neuroactive," one skilled in the art would not know what properties and activities the claimed proteinoid would have. Thus, the term "neuroactive" renders the claims indefinite.

Enablement Rejection of Claims 26-30, 32 and 33

Applicant argues the specification enables the claimed neuroactive proteinoid because it describes using P5, P6 and P8 to increase the firing rate of brain cells. However, the results cited by Applicant are prophetic as noted by the Board when it stated Applicant's results were "circumstantial and preliminary." Furthermore, the specification does not describe the experimental conditions under in which the proteinoids demonstrated neuroactivity. Thus, one skilled in the art would have to perform undue experimentation in order to practice the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
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